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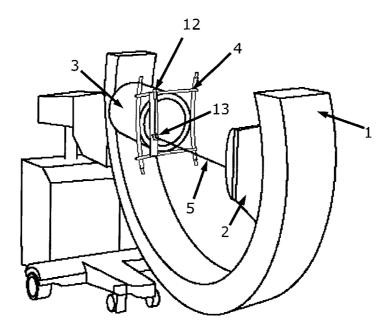
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(54) Title: POINTER FOR A RADIOGRAPHIC DEVICE



(57) Abstract: A radiographic device with a pointer adapted to point at an object of interest in a radiographic image and to visualize a corresponding reference point on a subject, e.g. a person or an animal being subject to medical examination. Thus facilitating the alignment of medical tools. The pointer comprises radiographically visible targeting means, and light emitting aiming means being attached to the targeting means in the pointer. The aiming means emits light in a direction substantially parallel to the electromagnetic radiation towards the subject independent of position of the aiming means in relation to the radiographic device.





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POINTER FOR A RADIOGRAPHIC DEVICE

Field of the invention

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The present invention relates to a radiographic device with a pointer adapted to point at an object of interest in a radiographic image and to visualize a corresponding reference point on a subject, e.g. a person or an animal being subject to medical examination.

10 Description of the prior art

A radiographic device, e.g. a real time X-ray device, may be used during surgery in an operating room. An X-ray device is normally used in orthopaedic alignment procedures, as well as in instrumentation of bones, e.g. in fastening of a femur nail via a transverse bore 15 in the bone and the nail, sampling of tumour-suspicious tissue or insertion of fixation devices. The use of X-rays is often prolonged, as the surgeon needs to insure correct position of tools in three dimensions. In particular, the locking bolts used with femur nails might prove a challenge to the surgeon. In such operations, the surgeon, in an X-ray image, locates a pre-defined bore of a nail inserted into the femur. Based on the image, 20 the surgeon drills a connecting bore through the femur bone for the insertion of the locking bolt through the bone and the nail. Careful orientation of the bone with the inserted nail is of utmost importance. Accordingly, an X-ray device displaying real time updated TV-screen images of the femur is appreciated in order to, constantly, monitor the operation and, in particular, to monitor the orientation of the bore in the nail. Typically, the X-ray device has 25 to be moved approximately 90° 6-8 times and since the X-ray device is not sterile, this is done through oral command from the surgeon to an operation assistant, thereby allowing for confusing, misunderstanding, and overuse of X-ray radiation. The inertia of the X-ray device prevents a precise centring of the subject and during the subsequent use of tools, the surgeon has to rely heavily on the ability to adjust manually for parallax error. Often 30 this is not complied with a high success rate.

To facilitate the alignment pointer devices, which use laser light as aiming means to point along the centre ray of the X-rays emitted by the X-ray device, have been disclosed. In these pointers an X-ray absorbing cross is used as a targeting means. The cross is fastened onto the X-ray device such that it is visible in the centre of the real time images displayed on the TV-screen. Before the surgeon starts drilling in the bone, he ensures that the direction of the drill, which will be the direction of the fastening hole, is parallel to the direction of the locking hole in the nail. The locking hole in the femur nail appears, in the TV-screen, as a bright hole in the outline of the nail. In the case where the plane of the

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locking hole is parallel to the detector plane, the bright hole appears round in the TV-screen, if the plane is tilted the bright hole appears oval or skewed. Furthermore, the surgeon ensures that the position of the laser spot marks the position of the locking hole. In order to ensure these two aspects, the surgeon should simultaneously orient and position the subject with respect to the radiographic device, such that:

- he makes sure that the image of the bore hole on the TV screen is perfectly round, and
- that the centre of the locking hole is at the centre of the target cross. In this case the laser spot on surface of the bone marks the position of the locking hole of the nail inside the bone.

This simultaneous orientating and centring is a tedious and slow procedure implying the aforesaid inconveniences as well as risks of faults. Furthermore, an x-ray device is very heavy and difficult to move around.

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Below follows some examples of prior art documents showing laser-targeting solutions.

U.S. Patent No. 5,426,687 discloses a laser-targeting device for use during surgical procedures providing means for the precise co-axial alignment of a narrow laser beam with an x-ray beam. The device has a housing, which contains a reflecting mirror mounted at 45° on a low mass assembly. The mirror lies directly in front of a radio-opaque cruciform target. The case is adjustably mounted so that the image of the crosshair target may be accurately centered on the target head. A calibration aid is used to pinpoint the emanation point of the z-ray beam from the source cone of the image intensifier. The angle at which the laser strikes the mirror may be varied in two planes.

U.S. Patent No. 5,537,453 discloses a coaxial laser targeting device for use with x-ray equipment. The device includes an x-ray transparent housing, which encloses a gimbal platform that may be adjustably inclined in any direction. A laser source supplies light
30 through an optical fiber to a lens assembly in the center of the gimbal platform and directs light through a laser-emitting aperture in the housing. Three adjustment members arranged in a triangular configuration are used to incline the gimbal platform in any direction relative to the housing to angularly align the laser beam with an x-ray equipment so that the beams are coaxial.

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U.S. Patent No. 5,644,616 discloses a method and apparatus for aligning a first radiation source (x-ray), with a beam from a second radiation source (laser), whereby structures internal to an object imaged with the first radiation can be located using the beam of second radiation. The light beam is directed by means of a mirror, which is transparent to

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the first radiation, for example an x-ray transparent mirror, along the axis of a calibrating tube. The calibrating tube has two radio opaque cross hairs at the opposite ends which are visualised on the fluoroscope's TV monitor, and when the cross-hairs of the calibration tube are superimposed on one another the line running from the intersection of the cross-hairs is collinear with the x-ray.

U.S. Patent No. 6,267,502 discloses a device and method for verifying positional alignment between a visible light beam and an x-ray field. The image of the radio-opaque body provides an indication of whether the position of the visible light beam is collinear and coincident with the central ray of the x-ray beam of an imaging system.

However the above examples of laser-targeting solutions aligns the laser beam with the center x-ray beam, in order to ensure that the direction of e.g. a bore is aligned with the center of the hole appearing at the monitor. However if the patient moves after alignment the surgeon has to readjust the patient or the x-ray device such that the hole is aligned with the central axis of the x-ray in order to ensure that the laser beam indicates the correct direction, as the laser beam only can have a direction being parallel to the central axis of the X-ray. Thus, it cannot compensate for the spherical dispersion of the x-rays.

U.S. Patent application No. 2002/0115932 discloses an embodiment of a targeting system comprising a penetrating beam emitter, a penetrating beam receiver, and a targeting assembly. The targeting assembly is adjustable. The targeting assembly has a targeting marker in a path of a penetrating beam provided by the emitter. The targeting marker is at least partially opaque to a penetrating beam emitted by the emitter, and the targeting marker indicates a targeting point on a target axis. The targeting assembly further includes a targeting beam device capable of providing a targeting beam along the target axis.

The example above shows a device, which only provides a limited region of accessibility of a targeting beam within the region of the x-ray beam. Furthermore the device is complex to operate, thus it will be time consuming to manually adjust and therefore it is inconvenient for both the operator and the client. Therefore it is necessary to control the device by a computer which further implies that it is not ultimate to use the device in an environment where the demand of cleanliness is high.

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EP 0 898 937 discloses a method and device for positioning a radiology instrument.

<u>Description</u> of the invention

The preferred embodiments of the present invention as hereinafter disclosed, greatly facilitate proper positioning as well as orientation of a subject subdued to treatment which require orientation and positioning by the use of a radiographic device.

In a first aspect, the present invention relates to a pointer for a radiographic device for pointing out a reference point during orthopaedic alignment procedures in medical treatment of a subject and comprising:

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- radiographically visible targeting means, and
- light emitting aiming means being attached to the targeting means in the pointer,
 and
- wherein said aiming means emits light in a direction substantially parallel to the electromagnetic radiation towards the subject independent of position of the aiming means in relation to said device.
- In a second aspect, the invention is used to locate objects of interest in a radiographic
 image and to visualize a corresponding spot on the exterior surface of the subject being
 medically examined, e.g. a point of entry. The invention thus relates to a pointer for a
 radiographic device for pointing out a reference point during orthopaedic alignment
 procedures in medical treatment of a subject. The pointer comprises:
- 25 radiographically visible targeting means, and
 - light emitting aiming means,

wherein the aiming means is attached to the targeting means in the pointer.

30 The below mentioned features both relate to the first and second aspects.

Since the aiming means is attached to the targeting means, the surgeon can reposition the pointer within the radiographic image. For example, if the surgeon position the targeting means so that it appears in the point if interest, the aiming means is simultaneously

positioned to aim at the same point in the object. The alignment procedure is thus possible with less reorientation of the patient.

In the preferred embodiment of the pointer, the pointer may be moved away from the centre axis of the radiographic device, and the pointer can be positioned independently with respect to the position of the detector.

5 If the pointer is moved, the pointer should be forced to aim in the direction where the fastening hole should be drilled, irrespectively of the position of the pointer. In this case, the surgeon only needs to orient the patient with respect to the radiographic device such that the locking hole is observed as a perfectly round image on a screen displaying live updated radiographic images of the object of interest. Subsequently, by centring the target cross in the centre of the locking hole, the direction along which the fastening hole should be drilled, as well as the point on the exterior surface corresponding to the centre of the fastening hole, are shown directly by the aiming means.

This facilitates greatly the alignment of the subject since the orientation and positioning of the subject, can be achieved without ensuring that the point of interest is located along the centre axis of the radiographic device.

In a radiographic X-ray device, the X-rays are emitted from a centre point of the emitter into a propagation cone with a relatively wide opening angle. A spherical surface is defined where the centre point of the sphere is coincident with the starting point of the propagation cone.

The pointer is attached to a holder that limits the freedom of the pointer motion, so that the pointer can be moved along a section of the aforementioned sphere. The holder itself 25 could be attached to the detector of the radiographic device. It may be attached onto the detector without modifications to an existing detector by using a flexible band, such as a clamp or clip, which comprises means for mounting the holder onto the band. A flexible band can be positioned in a range of locations onto the detector, thus allowing for different distances between the spherical surface defined by the holder, and the centre point. The 30 holder may comprise at least two intersecting sliding bars supporting another bar or plate (a pointer support bar), onto which the aiming means and the targeting means are fixed attached, as well as a fixed frame to support the sliding bars. The shape of the bars is such that the bars constitute a section of a great circle with the same radius as the distance between the centre point (coincident with the starting point of the propagation cone) and 35 the pointer. Thus, as the pointer and thereby the aiming means moves along said spherical surface, the aiming means will always point towards the starting point so that the surgeon only has to align the aiming means in relation to the hole to be drilled and not to the emitter, as the direction given by the aiming means in relation to the emitter always will be correct.

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The sliding bars could be made in a deformable material, e.g. the plastic material POM, any other plastic materials, stainless steel, titanium or other metals or alloy materials or flexible compounds which may be deformed. The pointer support bar could likewise be made from the same materials as the sliding bars, but preferably from a plastic or compound material which are substantial transparent to the electromagnetic radiation used, e.g. X-rays. By using deformable sliding bars the radius of curvature may be changed, this enables that the holder can be adjusted to fit onto different commercial C-arm devices, as the size of the arm in C-arm devices may vary a bit from model to model.

The sliding bars could comprise at least one adjustment screw that deforms the bar upon adjustment of the screw. However, in order to deform the bars into a smooth curve, several screws may be arranged between the fixed frame and the deformable bar, e.g. one screw for each 5 cm, 10 cm, or whatever distance that gives the optimal result for the

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material chosen.

The pointer may be positioned within the holder by moving it manually, by adjusting a screw, e.g. a micro-meter screw, by turning a handle, or by using servo motors or stepper motors which would ensure easy and precise positioning. The holder could include means for fixing the chosen position of the pointer, e.g. a clamp or a screw.

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The target means should preferably be clearly observable on the image generated from the electromagnetic radiation, and the target means could be formed as a cross-hair made from a material which absorbs a certain fraction of the type of radiation which is used. The material for the targeting means could be chosen from the group consisting of: lead, stainless steel, gold, silver, platinum, palladium, wolfram, tantalum, or any other metal or alloy which absorbs the electromagnetic radiation used. Typically, the electromagnetic radiation would be in the form of X-rays.

The aiming means should preferably be a focused light source which is clearly visible to the human eye, but an infrared or an ultra-violet source can also be used, in these cases, however, the surgeon needs to work with goggles that transform the light into visible light. The preferred light source is a diode laser. A small red diode laser is clearly visible by the human eye, the colour of the laser may also be blue, green or any other colour. The light from the light source could after emission from the source be redirected to run along a different direction by using a mirror. By using a mirror, it is possible to arrange the laser outside the detection field of the radiographic device or in the outer part of the detection field, e.g. attached to the edge of the pointer. To minimize shadowing from a mirror onto the screen, the mirror could be made in a material which is at least partly transparent to the electromagnetic radiation. This can be obtained by using a mirror comprising a thin

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reflective metal coating, e.g. rhodium, aluminium-magnesium alloy, aluminium-quarts or silver, evaporated onto a glass- or plastic-material. The size of the mirror is not crucial. It should be slightly larger than the spot size of the laser, so that the entire ray is redirected.

5 The aiming light ray should after passing the mirror be pointing along the direction between the target point and the centre point. This may be achieved by shining the light onto a mirror such that the reflection point on the mirror is on the axis between the target point and the centre point, and where the mirror is tilted with an angle such that the light, after passing the mirror, runs along this axis. It may be advantageous to provide a pointer where the angle of the mirror might be adjusted. The mirror would normally be quite small and positioned such that its centre is coincident with the centre of the cross-hair. Thus the mirror would be positioned inside the electromagnetic radiation used for generating the image. In this case, adjustment means for adjusting the angle of the mirror would be seen in the radiographic image, and such means could therefore, for certain purposes, be inconvenient. It would, therefore, be advantageous to fix the mirror to a certain position and certain angle, and provide means for adjusting the position and the angle of the laser with respect to the mirror. In this way the direction of the light ray emerging from the surface of the mirror can be controlled by adjusting the position and the angle of the light source.

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In another preferred embodiment, the pointer and the holder is incorporated into the detector of a radiographic device. In this preferred embodiment the pointer and the holder is mounted behind the protective screen of the detector. The protective screen should in this case be transparent to the type of light used for aiming. The curvature of the sliding bars should be adapted to match the dimensions of the C-arm. The control of the position of the pointer within the holder should be automatic or semi-automatic. The position of the pointer may be controlled via an external unit, or via a software solution, adapted to move the pointer to a requested position. For this reason, the software may comprise image analysis capability for automatic recognition of items of interest.

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The radiographic device is normally not sterile. If the surgeon needs to touch the pointer, a sterile transparent plastic shroud could be wrapped around the pointer and the detector. Ordinary plastic shrouds should not pose problems with respect to the laser beam otherwise shrouds with an anti-reflex coating on the inside may be used.

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The invention provides a mechanical device, which is manually operated and is easy to clean, therefore it is suitable for being used in environment wherein the demand of cleanliness is high. The mechanical device can preferably be used in the whole effective area of an x-ray beam, thus it is not restricted to a sub region of the x-ray beam.

In a third aspect, the invention relates to a method for alignment of a tool in relation to the point of interest in an object by means of a pointer comprising radiographically visible targeting means, and light emitting aiming means which is attached to the targeting

- 5 means, said method comprising the steps of:
 - arranging a radiating means that transmits electromagnetic radiation on one side of the point of interest,
- arranging a detecting means that detects electromagnetic radiation on an opposite side of the point of interest so that an image is formed which is based on the detected 10 electromagnetic radiation, the detecting means being arranged so that the formed image comprises an image of the point of interest,
 - arranging the targeting means of the pointer independently from the detecting and the radiating means so that the targeting means is visible in the image and so that its position in the image is substantially coincident with the point of interest, and
 - aligning the tool by means of a light spot formed by the aiming means.

The internal structure in a compact object may be hidden from the human eye. Situations may arise where it is necessary to insert an object from the outside in order to modify or 20 probe the internal structure. In such situations, a radiographic device may prove crucial to a successful modification of an internal structure. If the internal structure is known from e.g. drawings, but the orientation of the internal structure is hidden, the internal structure may be oriented by using the above mentioned method. The method could be used for medical as well as non-medical purposes.

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Detailed description of the invention

A preferred embodiment of the invention will now be described in details with reference to the drawings in which:

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- Fig. 1. is a C-arm radiographic device,
- Fig. 2. is a C-arm radiographic device with a human subject inserted,
- Fig. 3. is a schematic drawing of a C-arm, and
- Fig. 4. is a preferred embodiment of the pointer.

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In the following description of the invention the radiographic device is an X-ray C-arm device.

In Fig. 1 a schematic drawing of a standard C-arm device **1** is shown. The C-arm comprises an X-ray emitter **2** and an X-ray detector **3**. The holder **4** is mounted onto the detector. The pointer comprises an aiming means in the form of a laser **12** shining a laser beam **5** onto a mirror **13**.

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In Fig. 2 the C-arm device of Fig. 1 is shown with a patient **6** inserted between the X-ray emitter **2** and the X-ray detector **3**. The patient lies on a table **7**. The laser beam **5** points at a point of interest, i.e. a femur nail inserted into the femur of the patient.

In Fig. 3 a schematic drawing to illustrate various geometric features is provided. The X-ray emitter 2 and the X-ray detector 3 are mounted onto the arm of the C-arm device 1. The holder 4 is positioned in front of the detector 3. A cone of X-rays 9 is emitted from the detector. A sphere 10 is characterized by that the centre point 8 is coincident with the top point of the emission cone, and by that the radius of the sphere is equal to the distance between the centre point 8 and the centre of the holder 4.

In Fig. 4 a preferred embodiment of the pointer and holder is shown. This embodiment comprises 5 basic components. 1) A support bar **11**, 2) a light source **12**, 3) an X-ray transparent mirror **13**, 4) an x-ray absorbing cross **14**, and 5) a holder **21**, **22** and **23**.

The pointer is mounted in front of an X-ray detector **3**.

The holder comprises three sets of bars 21, 22 and 23. These bars are all curved with the same radius of curvature. This radius of curvature is equal to that of a sphere 10 where the centre point is coincident with the centre point of the emitter and where the radius is equal to the distance between the crossing point of the cross-hair 14 and the centre point of the emitter. Due to the curvature of the sliding bars the centre point of the support can be substantially positioned on a section of the spherical surface characterized above. Via a first set of bars 21, the entire holder and pointer are fixed to the detector. In a second set of bars 22, the bars are hollow with a hole diameter such that the second set of bars may slide on the first set of bars. A third set of bars 23 is mounted on the second set of bars. The sliding bars are made from the plastic material POM or from titanium. Low frictional material, e.g. PTFE, may be arranged in the plain bearing for reducing the friction. Alternatively, the joints may have ball bearings incorporated.

A support bar **11** is mounted on the holder. The purpose of this support is to secure the light source **12**, the x-ray absorbing cross **14**, and the deflecting mirror **13**. These entities constitute the pointer. The support bar is made from the plastic material POM. The movement of the pointer in the vertical direction is effectuated by the second set of bars **22** sliding on the first set of bars **21**, and likewise the movement in the horizontal direction is effectuated by the support sliding on the third set of bars **23**. The light source **12** is a low intensity red laser diode. The laser diode is fastened to the side of the support frame

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such that the light beam will hit the mirror 13 in a way such that the light beam is deflected along the axis pointing from the centre of the cross to the centre point of the emitter. The mirror is a thin metal layer, e.g. rhodium, evaporated onto a thin glass support. The mirror is highly X-ray permeable and only a little shadowing from the mirror is seen on the X-ray detector. The mirror can be positioned in any way that allows the light beam to run along the axis pointing from the centre of the cross to the centre point of the emitter. Here, this is achieved by mounting the light source such that the light beam hits the mirror tangential in conjunction with that the mirror is tilted 45 degrees with respect to the plane of the support bar 11. The X-ray detector is a standard C-arm X-ray detector.

10 With this embodiment of the pointer, a correct positioning of the holder onto the detector, as well as a correct radius of curvature for the sliding bars can easily be verified. This is achieved by ensuring that the light spot hits the central part of the X-ray emitter when no subject blocks the passage irrespective of the position of the pointer.

CLAIMS

1. A pointer for a radiographic device for pointing out a reference point during orthopaedic alignment procedures in medical treatment of a subject and comprising:

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- radiographically visible targeting means, and
- light emitting aiming means being attached to the targeting means in the pointer,
 and
- 10 wherein said aiming means emits light in a direction substantially parallel to the electromagnetic radiation towards the subject independent of position of the aiming means in relation to said device.
- 2. A pointer for a radiographic device for pointing out a reference point during orthopaedic 15 alignment procedures in medical treatment of a subject, the pointer comprising:
 - radiographically visible targeting means, and
 - light emitting aiming means
- 20 wherein the aiming means is attached to the targeting means in the pointer.
 - 3. A pointer according to claim 1 or 2, further comprising a holder allowing movement of the pointer and which guides the pointer to move along a section of a spherical surface with a centre point.

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- 4. A pointer according to any of the preceding claims, wherein the holder comprises attachment means for attaching the holder to a radiographic device.
- 5. A pointer according to claim 4, wherein the attachment means further comprise a 30 flexible band that can be mounted to the radiographic device in a range of positions.
 - 6. A pointer according to any of the claims 3-5, wherein the curvature of the spherical surface is adjustable.
- 35 7. A pointer according to any of claims 3-6, wherein the holder comprises at least two intersecting sliding bars supporting the pointer.
 - 8. A pointer according to claim 7, wherein the sliding bars are deformable via at least one adjustment screw.

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- 9. A pointer according to any of the claims 3-8, wherein the position of the pointer within the spherical surface of operation is controllable via adjustment means.
- 10. A pointer according to claim 9, wherein the adjustment means comprises at least one5 micrometer screw.
 - 11. A pointer according to claim 9, wherein the adjustment means comprises at least one servo motor.
- 10 12. A pointer according to any of the preceding claims, wherein the targeting means comprises a cross-hair made from a material which absorbs electromagnetic radiation, and where the crossing point of the cross-hair defines a target point.
- 13. A pointer according to any of the preceding claims wherein aiming means comprises a focused light source.
 - 14. A pointer according to claim 13 wherein the focused light source is a laser source.
- 15. A pointer according to any of the preceding claims further comprising a mirror for reflecting light emitted by the light source.
 - 16. A pointer according to claim 15 wherein the mirror is adapted to be at least partly transparent to the transmitted electromagnetic radiation.
- 25 17. A pointer according to claim 15 wherein the mirror is arranged in an orientation in relation to the light source so that the light is reflected from a reflection point on the mirror to the centre point.
- 18. A pointer according to claim 17, wherein the mirror is arranged so that the target 30 point, the reflection point on the mirror and the centre point is on a straight line.
 - 19. A pointer according to any of claims 3-18, wherein X-rays are emitted from a centre point of the device into a propagation cone, the centre point of said spherical surface being coincident with the starting point of the propagation cone.
 - 20. A radiographic device for medical examination of a subject and comprising:
 - a radiating part for transmission of electromagnetic radiation,
 - a detecting part for detecting electromagnetic radiation,

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- conversion means for converting the detected electromagnetic radiation to an image,
 and
- a pointer according to any of claims 1-19 for pointing out a point in the image and for pointing out a corresponding point on the subject,

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- said pointer is arranged between the subject and the collecting part and comprises aiming means arranged to emit light in a direction substantially parallel to the electromagnetic radiation towards the subject.
- 10 21. A device according to claim 20, wherein the pointer can be positioned independently with respect to the position of the detecting part.
- 22. A device according to claims 20 or 21, wherein the radiating part is arranged in relation to the pointer so as to radiate the electromagnetic radiation substantially from the15 centre point.
 - 23. A method for alignment of a tool in relation to point of interest in an object by means of a pointer comprising radiographically visible targeting means, and light emitting aiming means which is attached to the targeting means, said method comprising the steps of:

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- arranging a radiating means that transmits electromagnetic radiation on one side of the point of interest,
- arranging a detecting means that detects electromagnetic radiation on an opposite side
 of the point of interest so that an image is formed which is based on the detected
 electromagnetic radiation, the detecting means being arranged so that the formed
- electromagnetic radiation, the detecting means being arranged so that the formed image comprises an image of the point of interest,
 - arranging the targeting means of the pointer independently from the detecting and the radiating means so that the targeting means is visible in the image and so that its position in the image is substantially coincident with the point of interest, and
- 30 aligning the medical tool by means of a light spot formed by the aiming means.
 - 24. A method according to claim 23, wherein the aiming means is arranged to emit light in a direction substantially parallel to the electromagnetic radiation towards the subject.
- 35 25. A method according to claim 23 or 24, wherein the pointer is positioned on a holder allowing movement of the pointer and which guides the pointer to move along a section of a spherical surface with a centre point.

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26. A method according to any of claims 23-25, wherein the aiming means is fixed attached to the targeting means.

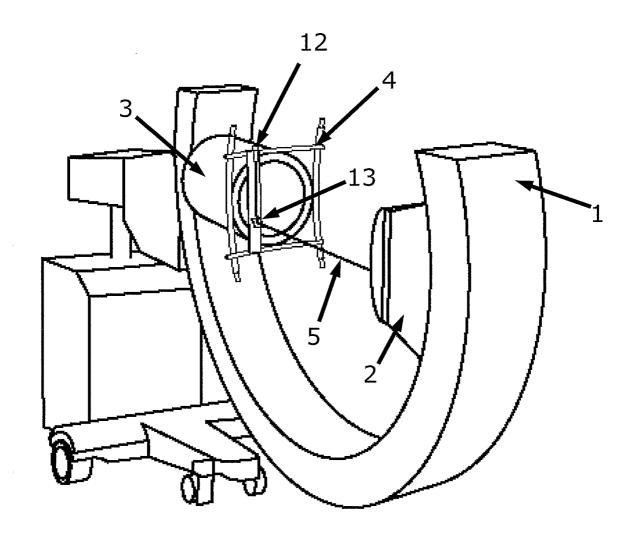


Fig. 1

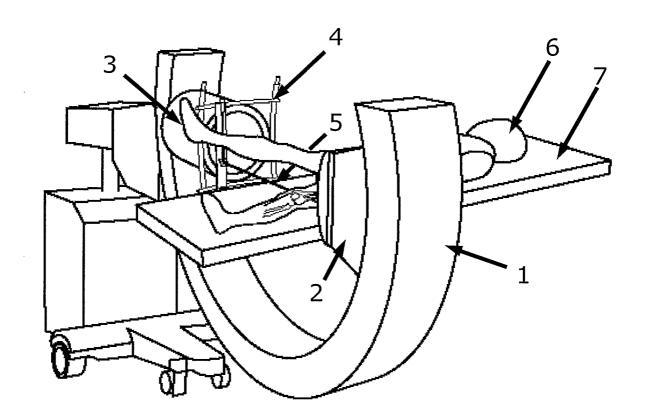


Fig. 2

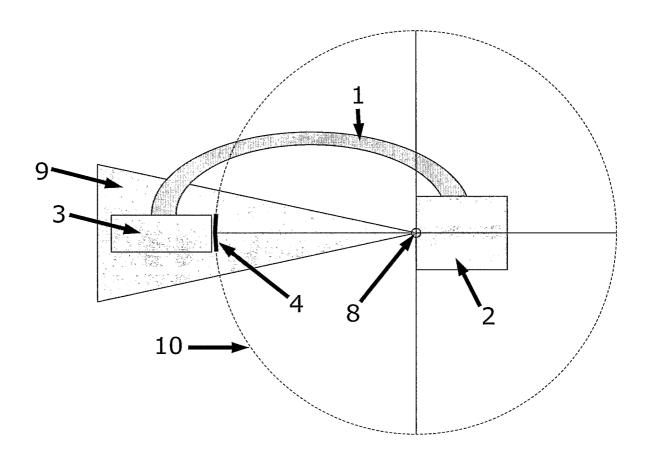
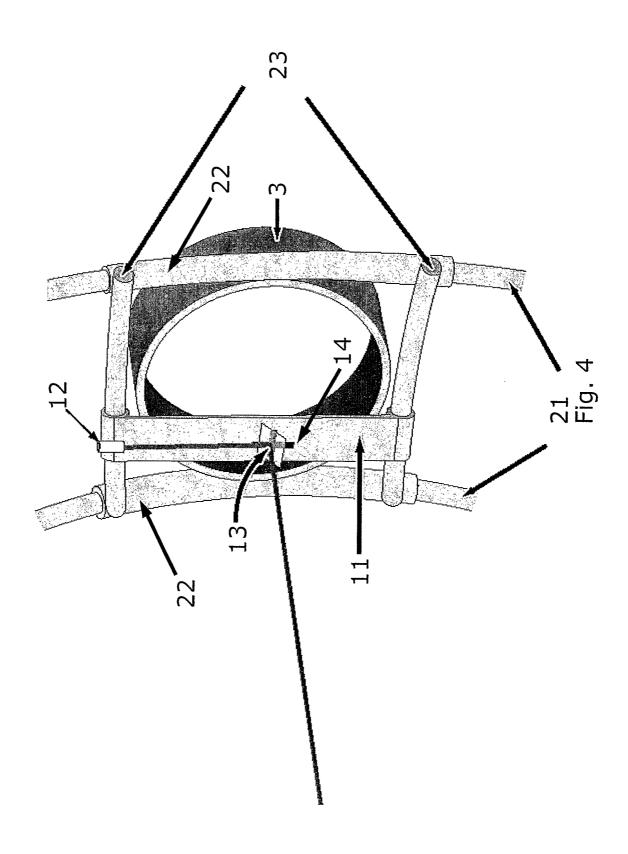


Fig. 3



INTERNATIONAL SEARCH REPORT

Ini tional Application No PCT/DK 03/00705

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61B6/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

 $\begin{array}{ll} \mbox{Minimum documentation searched (classification system followed by classification symbols)} \\ \mbox{IPC 7} & \mbox{A61B} \end{array}$

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMI	ENTS CONSIDERED TO BE RELEVANT		
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Х	US 5 537 453 A (WILLIAMS TERRY N 16 July 1996 (1996-07-16)	ET AL)	2,4, 12-14, 20-26
Α	column 4, line 17 - line 39 column 5, line 24 - line 42; figu	re 2	1
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χ Furti	l her documents are listed in the continuation of box C.	γ Patent family members are listed	in annex.
"A' docume consic "E' earlier of filing of "L" docume which citatio "O' docume other "P' docume later ti	december of particular relevance of the all which is not be of particular relevance document but published on or after the international date ent which may throw doubts on priority claim(s) or is cited to establish the publication date of another n or other special reason (as specified) ent referring to an oral disclosure, use, exhibition or means ent published prior to the international filing date but	"T" later document published after the inte or priority date and not in conflict with cited to understand the principle or the invention "X" document of particular relevance; the cannot be considered novel or cannot involve an inventive step when the do "Y" document of particular relevance; the cannot be considered to involve an involve and in the considered to involve an involve and in the art. "&" document member of the same patent Date of mailing of the international see	eary underlying the slaimed invention be considered to current is taken atone slaimed invention ventive step when the ore other such docuus to a person skilled
	O January 2004	27/01/2004	
Name and	mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer Mayer-Martenson,	E

INTERNATIONAL SEARCH REPORT

In tional Application No
PCT/DK 03/00705

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C.(Continu	ation) DOCUMENTS CONSIDERED TO BE RELEVANT			
Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
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